

## REMARKS

After entry of this response, claims 1-6 remain pending in the present application. Claims 1, 3 and 6 have been amended by this response. Support for the amendment of claim 1 can be found, for example, at paragraph 0047. Support for the amendment of claim 3 is inherent since the claim has been amended merely to obviate the deficiency of a proper antecedent basis for “the sensed parameters” recited in the originally presented claim. Support for the amendment of claim 6 can be found for example at paragraph 0041. Applicant respectfully requests reconsideration by the Examiner in light of the following remarks.

### **I. Rejection Under 35 USC § 102(b) (Nappholz)**

Claims 1-6 stand rejected under 35 USC 102(b) as being anticipated by Nappholz et al. (U.S. 5,113,869, hereinafter “Nappholz”). Applicant respectfully traverses this rejection to the extent the rejection may be considered applicable to the claims, as amended.

The Nappholz reference fails to disclose monitoring a drug delivery device for administration of a drug. In amended claim 1, for example, a monitoring system in a patient under a prescriptive regimen to take a drug from a drug delivery device monitors the administration of the drug and checks the drug interaction in the patient based on physiological signs measured subsequent to the drug intake. Nappholz performs monitoring of a patient’s physiological signals and upon detecting a triggering event, sends a control signal to a therapeutic device such as an infusion pump. *See* col. 21, lines 44-53. However, beyond sending the control signal to the therapeutic device, there is no teaching of monitoring the device’s administration of the drug.

Monitoring whether a drug has been administered by the drug delivery device ensures that the evaluation of physiological parameters is properly correlated to actual drug intake. Therefore, the system of amended claim 1, for example, determines whether a drug administration has been performed and monitors the effects and interaction of the drug in the patient. Thus, the system of the present application facilitates closed loop monitoring for the determination of the effects of a drug intake by a patient.

Accordingly, for at least the foregoing reasons, Applicant respectfully requests the withdrawal of the rejection under 35 USC 102(b) of claims 1-6 as being anticipated by Nappholz.

## **II. Rejection Under 35 USC § 102(b) (Ellinwood)**

Claims 3-6 stand rejected under 35 USC 102(b) as being anticipated by Ellinwood Jr. (U.S. 4,146,029, hereinafter "Ellinwood"). Applicant respectfully traverses the rejection.

Ellinwood provides a device and method for dispensing medication internally of the body whereby a particular body condition at a particular point in the body is sensed and the sensed data is used to control operation of a medication dispensing apparatus. *See* col. 3, lines 15-19. Ellinwood is deficient of a teaching of monitoring the parameters of a drug delivery device. Rather, the explicit teachings of Ellinwood disclose that the apparatus and method function on a basis of changes in body conditions with the changes controlling when the dispensing apparatus operates. By monitoring parameters of a drug delivery device, the system of claim 3, for example, facilitates a feedback mechanism for self administered drug regimen and correlation of drug administration with the monitored parameters.

Accordingly, for at least the foregoing reasons, Applicant respectfully requests the withdrawal of the rejection under 35 USC 102(b) of claims 3-6 as being anticipated by Ellinwood.

## **III. Conclusion**

In view of the foregoing, it is submitted that this application is in condition for allowance. Favorable consideration and prompt allowance of the application are respectfully requested. Should any issues remain outstanding, the Examiner is urged to telephone the undersigned to expedite prosecution. The Commissioner is authorized to charge any deficiencies and credit any overpayments to Deposit Account No. 13-2546.

Respectfully submitted,

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